(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
22 July 2004 (22.07.2004)

PCT

(10) International Publication Number
WO 2004/060214 A1

(51) International Patent Classification[7]: A61F 2/06

(21) International Application Number:
PCT/US2003/041317

(22) International Filing Date:
27 December 2003 (27.12.2003)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
60/437,092 30 December 2002 (30.12.2002) US

(71) Applicant and
(72) Inventor: **HESHAM, Morsi** [US/US]; 2058 Southgate Blvd, Houston, TX 77030 (US).

(74) Agent: **McEWING, David**; P.O. Box 231324, Huston, TX 77023 (US).

(81) Designated States *(national)*: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.

(84) Designated States *(regional)*: ARIPO patent (BW, GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PT, RO, SE, SI, SK, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

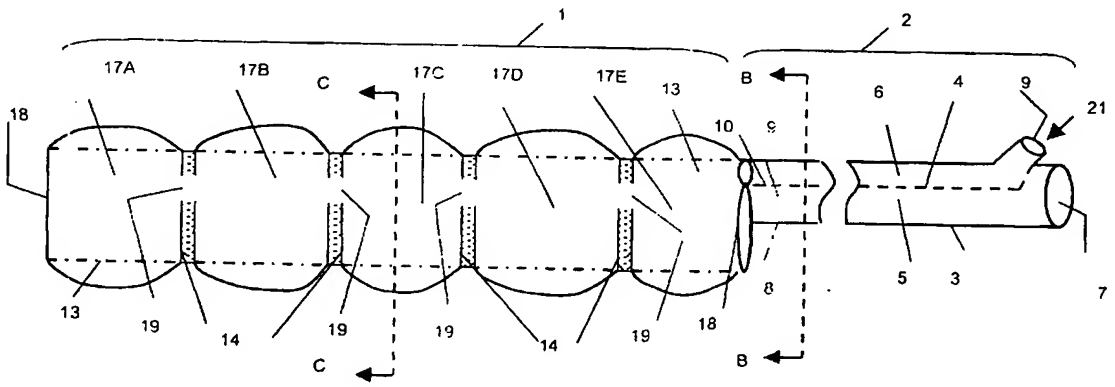
Declarations under Rule 4.17:
— *as to applicant's entitlement to apply for and be granted a patent (Rule 4.17(ii)) for the following designations AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, UZ, VC, VN, YU, ZA, ZM, ZW, ARIPO patent (BW, GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PT, RO, SE, SI, SK, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG)*
— *of inventorship (Rule 4.17(iv)) for US only*

Published:
— *with international search report*
— *with amended claims*

Date of publication of the amended claims: 2 September 2004

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: ENDOVASCULAR BALLOON GRAFT



(57) Abstract: A method and apparatus for repair of stenotic and aneurysmic vessels utilizing in situ deployment of an inflatable tubular shaped device (1) having a longitudinally oriented annulus (17). When inflated, the size and rigidity of the device (1) is increased, thereby providing supplemental strength to the vessel wall and a lumen (8) for the passage of fluid.

WO 2004/060214 A1

AMENDED CLAIMS
[received by the International Bureau on 23 July 2004 (23.07.04);
original claims 1-17 amended; new claims 18-57 added]

What I claim is

1. An inflatable tubular shaped graft comprising:
   a. a first outer wall;
   b. a second inner wall having a smaller diameter than the first outer wall;
   c. at least one fused juncture of the first and second wall that creates fluid impermeable seals and fluid communicating passages within a resulting interstitial space between the first and second wall; and
   d. a valve to convey fluid into the interstitial space to inflate the graft and create a lumen within the tubular graft.
2. The graft of claim 1 further comprising a plurality of junctures of the first wall and the second wall in a selected orientation wherein at least one juncture is intersected by at least one passage capable of conveying fluid within the interstitial space.
3. The graft of claim 2 wherein at least a portion of the selected orientation of the junctures is substantially circumferential.
4. The graft of claim 2 wherein a fused juncture of the first and second wall is variably sized to create a non-linear longitudinal axis of the graft.
5. The graft of claim 1 wherein the outer wall has a greater longitudinal length between each fused joint than the longitudinal length of the inner wall.
6. The graft of claim 1 wherein the inner and outer walls are comprised of materials having differing elasticity.
7. The graft of claim 1 wherein at least one of the inner and outer walls are comprised of non-elastic material.
8. The graft of claim 1 wherein at least one wall is comprised of a material selected from a group consisting of polyethylene, polyurethane, TFE, PTFE, and ePTFE.
9. The graft of claim 1 further comprising a fluid that can be communicated through the valve to fill the interstitial space.
10. The graft of claim 8 further comprising a component for locating the tubular shaped graft and inflating the graft with the fluid within a vessel lumen to form a lumen within the graft through which body fluids may be conveyed.

11. The graft of claim 1 further comprising radially oriented web reinforcement within one or more fluid communicating chambers within the interstitial space of the inner and outer walls.
12. The graft of claim 11 wherein the radially oriented web reinforcement is comprised of non-elastic material.
13. The graft of claim 11 wherein the radially oriented web reinforcement is comprised of material attached to the inner and outer walls in a corrugated manner and allowing fluid communication between the inner and outer walls within the interstitial space.
14. The graft of claim 13 wherein the material is comprised of a web of 2 or more inter-connected fibers.
15. The graft of claim 11 wherein the radially oriented web reinforcement maintains the spacing and orientation of the inner and outer graft wall after addition of fluid.
16. The tubular shaped graft of claim 1 having a first and second end wherein an outer diameter of the first graft end is different than the outer diameter of the second graft end.
17. The graft of claim 1 for treatment of aneurysms.
18. The graft of claim 1 for treatment of atherosclerosis.
19. The graft of claim 4 wherein after the interstitial space is filled with fluid, the outer wall forms a substantially corrugated surface and the inner wall forms a substantially smooth surface.
20. The graft of claim 9 wherein the fluid is a curable composition.
21. The graft of claim 20 wherein the curable composition is selected from the group consisting of a monomer, a liquid pre-polymer and an un-linked polymer.
22. A method for repair of vessel walls comprising the steps of:
    a. inserting a sealable two walled tubular shaped graft within the vessel lumen utilizing a catheter having a fluid conveying means in communication to a valve accessing an interstitial space between the two walls of the graft;
    b. maneuvering the graft to a selected location within the vessel lumen;
    c. inserting fluid through a controllable valve within the graft and into interstitial space between the two walls of the graft;

d. continuing the addition of fluid to deploy the graft in a radial direction sufficient that the one wall contacts the vessel wall and a lumen is created along the longitudinal length of the graft; and

e. withdrawing the catheter.

23. The method of claim 22 further comprising continuing the addition of fluid to increase the inner diameter of the graft lumen to a controlled size after the graft wall contacts the vessel wall

24. The method of claim 22 further comprising reinforcing the wall of the vessel with the fluid inflated graft.

25. The method of claim 24 further comprising reinforcing the vessel wall with the fluid stiffened graft wall.

26. The method of claim 22 further comprising using the inflated graft to isolate a diseased vessel wall from the vessel lumen.

27. The method of claim 22 further comprising using the radial expansion force of the inflating fluid to widen the vessel lumen.

28. The method of claim 22 further comprising using non elastic internal support attachments connecting the two walls of the graft to retain a desired shape and dimension of the graft after inflation with fluid.

29. The method of claim 28 further comprising varying the dimensions of the internal support attachments to create a corrugated outer surface on the outer wall of the graft after fluid inflation.

30. The method of claim 29 further comprising using the corrugated outer surface to facilitate the retention of the graft at a desired location within the vessel lumen after withdrawal of the catheter.

31. The method of claim 22 further comprising treating aneurysm.

32. The method of claim 22 further comprising treating atherosclerosis.

33. A method of treating aneurysm comprising the steps of:

a. inserting a flexible two walled tubular shaped graft within the vessel lumen utilizing a catheter having a fluid conveying component and where the graft further comprises

(i) two walls fluid sealed at each end of the graft and forming a fluid sealable interstitial space between the walls;

(ii) a plurality of connectors oriented in a substantially radial direction within the interstitial space and attached to the two walls;

(iii) a controllable valve accessing the interstitial space between the walls of the graft and attachable to the fluid conveying component of the catheter;

b. maneuvering the graft to a selected location within the vessel lumen proximate to the aneurysm;

c. inserting fluid through a controllable valve within the graft into the interstitial space between the two walls of the graft;

d. continuing the addition of fluid to deploy the graft in a radial direction sufficient that an outer wall of the graft contacts the vessel wall and a lumen is opened within the graft in communication with the vessel lumen;

e. continuing the addition of fluid to cause the graft wall to stiffen and isolate the aneurysm from the vessel lumen;

f. withdrawing the catheter; and

g. continuing use of the stiffened graft to reinforce the vessel wall, isolate the aneurysm and maintain the graft lumen in communication with the vessel lumen.

34. The method of claim 33 further comprising using a graft comprised of substantially non-elastic materials and of a selected inflated shape and dimension.

35. The method of claim 34 further comprising a non linear shaped graft selected for compatibility with the shape and dimension of the vessel lumen to be treated and orienting the graft to the vessel shape prior to the addition of fluid.

36. The method of claim 34 further comprising using a non linear shaped graft selected and dimensioned for compatibility with the vessel lumen to be treated and orienting the graft to the vessel shape prior to the completion of fluid addition.

37. The method of claim 34 further comprising inserting a graft containing at least one fenestration and orienting the fenestration to a branch of the vessel lumen.

38. A method of treating atherosclerosis comprising the steps of:

a. inserting a flexible two walled tubular shaped graft within the vessel lumen utilizing a catheter having a fluid conveying component and where the graft further comprises
   (i) two walls fluid sealed at each end of the graft and forming a fluid sealable interstitial space between the walls;
   (ii) a plurality of connectors oriented in a substantially radial direction within the interstitial space and attached to the two walls;
   (iii) a controllable valve accessing the interstitial space between the walls of the graft and attachable to the fluid conveying component of the catheter;
b. maneuvering the graft into an area of atherosclerosis within the vessel lumen;
c. inserting fluid through a controllable valve within the graft into the interstitial space between the two walls of the graft;
d. continuing the addition of fluid to deploy the graft in a radial direction sufficient that an outer wall of the graft contacts the vessel wall and the diameter of the vessel lumen is expanded and a lumen is opened within the graft in communication with the vessel lumen;
e. continuing the addition of fluid to cause the graft wall to stiffen and the graft lumen expand to a selected diameter;
f. withdrawing the catheter; and
g. continuing use of the stiffened graft to reinforce the vessel wall, maintain the expanded vessel lumen and maintain the graft lumen in communication with the vessel lumen.

39. The method of claim 38 further comprising using a graft comprised of substantially non-elastic materials and of a selected inflated shape and dimension.

40. The method of claim 39 further comprising using a non linear shaped graft selected for compatibility with the shape and dimension of the vessel lumen to be treated and orienting the graft to the vessel shape prior to the addition of fluid.

41. The method of claim 39 further comprising using a non linear shaped graft selected for compatibility with the shape and dimension of the vessel lumen to be treated and orienting the graft to the vessel shape prior to the completion of fluid addition.

42. A tubular shaped graft comprising:

a. a first hollow cylindrically shaped flexible component having an open first proximal end and a open second distal end and forming an outer wall of the graft;
b. a second hollow cylindrically shaped flexible component having a first open proximal end and a second open distal end and forming an inner wall of the graft;
c. a fluid impermeable seal joining the first ends of the first and second components and a fluid impermeable seal joining the second ends of the first and second components forming a two walled lumen;
d. a valve to convey fluid through the graft wall into an interstitial space between the sealed ends of the outer wall and inner wall of the lumen to inflate the graft;
e. a plurality of flexible connectors within the interstitial space and attached to the outer wall and inner wall.

43. The graft of claim 40 wherein the outer wall has an uneven surface and the inner wall has a smooth surface.
44. The graft of claim 40 wherein at least one of the group of connectors, inner wall or outer wall are substantially non-elastic.
45. The graft of claim 42 wherein the graft is of a pre-selected inflatable dimension and shape.
46. The graft of claim 42 wherein the connectors are of varying length to cause the outer wall surface to be corrugated.
47. The graft of claim 42 wherein the connectors are of varying length to cause the outer wall surface to be dimpled.
48. The graft of claim 42 wherein the interstitial space contains a plurality of chambers.
49. The graft of claim 48 wherein the chambers are formed by the inner and outer walls being joined together.
50. The graft of claim 42 wherein the inflated outer diameter is less than 10 mm.
51. The graft of claim 42 wherein the fluid inflating the graft is a curable composition.
52. The graft of claim 49 is curable composition is selected from the group consisting of a monomer, a liquid pre-polymer or an un-linked polymer.
53. The graft of claim 42 wherein the fluid inflating the graft contains saline.
54. The graft of claim 42 wherein at least one wall is comprised of a material selected from a group consisting of polyethylene, polyurethane, TFE, PTFE and ePTFE.

55. The graft of claim 42 wherein the outer diameter of the distal end is different from the outer diameter of the proximal end.

56. A non-linear tubular shaped graft comprising:

a. a first hollow cylindrically shaped flexible component having a open first proximal end and a open second distal end and forming an outer wall of the graft;

b. a second hollow cylindrically shaped flexible component having a open first proximal end and a open second distal end and forming an inner wall of the graft;

c. a fluid impermeable seal joining the first ends of the first and second components and a fluid impermeable seal joining the second ends of the first and second components forming a two walled lumen;

d. a valve to convey fluid through the graft wall into an interstitial space between the sealed ends of the outer wall and inner wall to inflate the graft; and

e. a plurality of flexible connectors within the interstitial space and attached to the outer wall and inner wall.

57. The graft of claim 56 further comprising one or more junctures of the first and second wall between the sealed first and second ends variably sized to create a nonlinear longitudinal axis of the graft after inflation with fluid.